DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 058

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 058" (Recognition List Number: 058), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Either electronic or written comments can be submitted on the notice at any time. These modifications to the list of recognized standards are applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2004-N-0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 058." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 058.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information

you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

An electronic copy of Recognition List Number: 058 is available on the internet at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 058 modifications and other standards-related information. Submit written requests for a single hard copy of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 058" to Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301-796-6580. Send one

self-addressed adhesive label to assist that office in processing your request, or Fax your request to 301-847-8144.

FOR FURTHER INFORMATION CONTACT: Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301-796-6580, CDRHStandardsStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the *Federal Register* of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." The guidance describes how FDA has implemented its standards recognition program and is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. Modifications to the initial list of recognized standards, as published in the *Federal Register*, can be accessed at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website HTML and PDF versions of the list of FDA Recognized Consensus Standards, available at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents. Additional information on the Agency's Standards and Conformity Assessment Program is available at

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

II. Modifications to the List of Recognized Standards, Recognition List Number: 058

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term "Recognition List Number: 058" to identify the current modifications.

In table 1, FDA describes the following modifications: (1) the withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 058.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Anesthesiology			
No new entries at this time.			
B. Biocompatibility			
2-174	2-296	ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices--Part 10: Tests for skin sensitization.	Withdrawn and replaced with newer version.
C. Cardiovascular			
3-116	3-181	ISO 25539-2 Third edition 2020-09 Cardiovascular implants--Endovascular devices--Part 2: Vascular stents.	Withdraw and replaced with newer version.
3-137	3-182	ASTM F3036-21 Standard Guide for Testing Absorbable Stents.	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4-236	4-293	ANSI/ADA Standard No. 119-2021 Manual Toothbrushes.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
No new entries at this time.			
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
19-4	19-46	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)].	Withdrawn and replaced with newer version.
19-16	19-47	ANSI/AAMI HA60601-1-11:2015 Medical Electrical Equipment--Part 1-11: General requirements for basic safety and essential performance--Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including AMD 1:2021].	Withdrawn and replaced with newer version.
19-30	19-45	AIM Standard 7351731 Rev. 3.00 2021-06-04 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers--An AIM Standard.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6-174	6-475	ISO 11608-4:2022 Needle-based injection systems for medical use--Requirements and test methods--Part 4: Needle-based injection systems containing electronics.	Withdrawn and replaced with newer version.
6-275	6-476	ISO 11608-2:2022 Needle-based injection systems for medical use--Requirements and test methods--Part 2: Double-ended pen needles.	Withdrawn and replaced with newer version.
6-294	6-477	ISO 11608-3:2022 Needle-based injection systems for medical use--Requirements and test methods--Part 3: Containers and integrated fluid path.	Withdrawn and replaced with newer version.
6-341	6-478	ISO 11608-1:2022 Needle-based injection systems for medical use--Requirements and test methods--Part 1: Needle-based injection systems.	Withdrawn and replaced with newer version.
6-377	6-479	ISO 11608-5:2022 Needle-based injection systems for medical use--Requirements and test methods--Part 5: Automated functions.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7-303		CLSI M60 2nd Edition Performance Standards for Antifungal Susceptibility Testing of Yeast.	Extent of recognition.
I. Materials			
8-336	8-583	ASTM F562-22 Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035).	Withdrawn and replaced with newer version.
8-347	8-584	ASTM F2146-22 Standard Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320).	Withdrawn and replaced with newer version.
8-354	8-585	ASTM F1377-21 Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538).	Withdrawn and replaced with newer version.
8-362	8-586	ASTM F2989-21 Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8-447	8-587	ISO 5832-3 Fifth Edition 2021-11 Implants for surgery--Metallic materials--Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.	Withdrawn and replaced with newer version.

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
8-469	8-588	ASTM F560-22 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400).	Withdrawn and replaced with newer version.
8-471	8-589	ASTM F1925-22 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.	Withdrawn and replaced with newer version.
8-525	8-590	ISO/TS 17137 Third Edition 2021-09 Cardiovascular implants and extracorporeal systems--Cardiovascular absorbable implants.	Withdrawn and replaced with newer version.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
10-110	10-131	ISO 15798 Fourth edition 2022-01 Ophthalmic implants--Ophthalmic viscosurgical devices.	Withdrawn and replaced with newer version.
N. Orthopedic			
No new entries at this time.			
O. Physical Medicine			
16-166		ISO 7176-21 Second edition 2009-04-01 Wheelchairs--Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	Extent of recognition
P. Radiology			
12-277	12-343	IEC 62127-1 Edition 2.0 2022-03 Ultrasonics--Hydrophones--Part 1: Measurement and characterization of medical ultrasonic fields.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14-478	14-572	ANSI/AAMI ST91:2021 Flexible and semi-rigid endoscope processing in health care facilities.	Withdrawn and replaced with newer version.
14-482	14-573	ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials.	Withdrawn and replaced with newer version.
14-496	14-574	ASTM F1608-21 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).	Withdrawn and replaced with newer version.
14-497	14-575	ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.	Withdrawn and replaced with newer version.
14-499	14-576	ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.	Withdrawn and replaced with newer version.
14-514	14-577	ISO 11737-1 Third edition 2018-01 [Including: AMD1 (2021)] Sterilization of health care products--Microbiological methods--Part 1: Determination of a population of microorganisms on product [Including: Amendment 1 (2021)].	Withdrawn and replaced with newer version.
14-515	14-578	ISO 17664-1 First edition 2021-07 Processing of health care products--Information to be provided by the medical device manufacturer for the processing of medical devices--Part 1: Critical and semi-critical medical devices.	Extent of Recognition. Withdrawn and replaced with newer version.
S. Tissue Engineering			
No new entries at this time.			

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 058. These entries are of standards not previously recognized by FDA.

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Anesthesiology		
1-152	Medical electrical equipment--Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators.	ISO 80601-2-87 First edition 2021-04.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
No new entries at this time.		
D. Dental/ENT		
No new entries at this time.		
E. General I (QS/RM)		
15-135	Medical devices--Information to be supplied by the manufacturer.	ISO 20417 First edition 2021-04 Corrected version 2021-12.
F. General II (ES/EMC)		
No new entries at this time.		
G. GH/GPS		
6-480	Needle-based injection systems for medical use--requirements and test methods--Part 6: On-body delivery systems.	ISO 11608-6:2022.
6-481	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications.	ANSI/AAMI CN27:2021.
6-482	Fluid delivery performance testing for infusion pumps.	AAMI TIR101:2021.
H. IVD		
7-312	Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data.	CLSI M39 5th Edition.
I. Materials		
8-591	Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108).	ASTM F2229–21.
8-592	Standard Specification for Polydioxanone Polymer Resins for Surgical Implants.	ASTM F3384–21.
8-593	Implants for surgery--Hydroxyapatite--Part 6: Powders.	ISO 13779-6 First edition 2015-01-15 Corrected Version 2016-09-15.
J. Nanotechnology		
No new entries at this time.		
K. Neurology		
No new entries at this time.		
L. OB-Gyn/G/Urology		
9-139	Colorimetry--Part 5: CIE 1976 L*u*v* colour space and u',v' uniform chromaticity scale diagram.	ISO/CIE 11664-5:2016.
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
No new entries at this time.		
O. Physical Medicine		
No new entries at this time.		
P. Radiology		

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
12-344	Medical electrical equipment--Medical image display systems--Part 2: Acceptance and constancy tests for medical image displays.	IEC 62563-2 Edition 1.0 2021-11.
12-345	Evaluation and routine testing in medical imaging departments--Part 3-7: Acceptance and constancy tests--Imaging performance of X-ray equipment for dental cone beam computed tomography.	IEC 61223-3-7 Edition 1.0 2021-12.
Q. Software/Informatics		
No new entries at this time.		
R. Sterility		
14-579	Processing of health care products--Information to be provided by the medical device manufacturer for the processing of medical devices--Part 2: Non-critical medical devices.	ISO 17664-2 First edition 2021-02.
S. Tissue Engineering		
No new entries at this time.		

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. Such standards are those that FDA has recognized by notice published in the *Federal Register* or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the *Federal Register*). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the *Federal Register* once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to CDRHStandardsStaff@fda.hhs.gov. To be considered, such recommendations should contain, at a minimum, the information available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-17150 Filed: 8/9/2022 8:45 am; Publication Date: 8/10/2022]